Missouri Department of Health and Senior Services'

BUREAU OF NARCOTICS & DANGEROUS DRUGS

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DEA Contacted on Schedule II Prescription Questions

The DEA has published information saying that pharmacists can no longer make changes to "essential" parts of a Schedule II prescription.

In response to questions from the industry, the BNDD called the DEA to verify the information. The bureau spoke with both the Midwest DEA District Office and the Liaison and Policy Unit at DEA headquarters. The BNDD received consistent answers from both offices.

What are considered the "essential" parts of a prescription?

The essential parts are all parts and requirements listed in federal regulation 21 CFR 1306.05(a). All these parts are required and may not be changed on Schedule II prescriptions:

- Date written;
- Patient's full name;
- Patient's full address;
- Drug name;
- Drug strength;
- Drug form;
- Quantity to be dispensed;
- Directions for use;
- Prescriber's address;
- Prescriber's DEA number;
- Prescriber's manual signature.

Although a pharmacy may not change an item, can they add an item such as a patient's address or DEA number?

The pharmacy cannot make a change to the prescription issued by the prescriber. If the pharmacy adds something, it is changing what was originally provided. Adding something is changing it.

BNDD will continue to provide updates and information as it comes available.

Meth-Precursor Tracking Database

Legislation was enacted in 2008 that would allow the state of Missouri to implement a statewide database for the real-time tracking of ephedrine and pseudoephedrine sales. Although the legislation was enacted the funding was not available at the time.

During the past 6 months, multiple companies came forward and offered database services that would be free to the state of Missouri. The state underwent a formal competitive bid process in which bids were submitted and then evaluated by a committee.

The bid was awarded to Appriss Inc. of Louisville, Ky. Representatives of Appriss will be meeting with the BNDD in early April to review possible rules and processes for building the database and bringing it on line. The BNDD will be filing rules regarding the database.

Approximately 80 percent of Missouri retail pharmacies are national chain stores, which can be brought online rather quickly. The remaining 20 percent, which are independent stores, will be brought online as soon as possible. The contract with Appriss includes training for retail pharmacy employees and law enforcement agencies. These training sessions will take place at regional locations around the state so that parties involved may attend a course in their area. Course material will be available online and will be supported by a 24-hour help desk.

Before a purchase can be made, a customer's government-issued ID must be checked through the database. The system will notify the pharmacy of previous purchases and will notify the pharmacy whether the sale should be permitted.

Current Scheduling Actions

Bills currently moving through the Missouri Legislature would update the list of controlled substances. The bills now being debated carry an emergency clause, which would make the following drugs controlled substances immediately upon the bills being signed by the Governor:

- Lacosamide to Schedule 5;
- Tapentadol to Schedule 2;
- Fospropofol to Schedule 4;
- 5-MeO-DMT to Schedule 1
- Three anabolic steroids added to Schedule 3
  - Boldione;
  - Desoxymethyltestosterone;
  - 19-nor-4,9(1)-androstadienedione

- Synthetic cannabinoids – Spiced cannabinoids "K2" to Schedule 1:
  - Indole, or 1-Pentyl-3-(1-naphthoyl)indole
  - Indole, or 1-Butyl-3-(1-naphthoyl)indole
  - Phenol, or CP 47,497 and homologues or 2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol)
  - Dexanabinol, or HU-211 or (dexanabinol, (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol

Electronic Prescribing Rules:

The BNDD wishes to remind all registrants that the DEA will be publishing an interim final rule on March 31, 2010, regarding electronic prescriptions for controlled substances.

There are several important factors to note:

1. This is an interim final rule and not the final rule;
2. The DEA is seeking more public comments;
3. The final rule is yet to be published;
4. A rule will eventually go into effect, 60 days after the official final rule is published;
5. When the final rule is adopted, registrants will be allowed to conduct electronic prescribing only after their system meets all the criteria set forth by the DEA for hardware, software, encryption, security and record keeping.

The BNDD does not anticipate having state rules for electronic prescribing that are more restrictive than the federal DEA rules. Once the BNDD can see the final federal rules, the BNDD will move to have the existing state rules amended to incorporate and match the federal rules for electronic prescribing.

Practitioners are reminded not to begin electronically prescribing until the final rule is in effect and they have verified that their processes meet federal regulations.

U.S. Senate Hearing Over Prescriptions for LTCF Patients

On March 24, members of the long-term care industry made a presentation before the U.S. Senate Special Committee on Aging regarding the challenges associated with prescriptions in residential facilities.

The industry representatives reported that some patients linger in pain while facilities attempt to obtain proper prescriptions. They told of having to hunt down doctors to obtain required information on prescriptions so patients could receive their medication. They discussed the problem of nurses in LTCFs not being considered "agents" of the doctors.

They said their industry has changed since the original Controlled Substances Act of 1970. The industry representatives expressed their desire to cooperate with the DEA to make changes to current regulations.

The DEA and the National Association of Boards of Pharmacies also testified. They said they also would be interested in cooperating to address possible changes.

Points raised were:

- The DEA does not register LTCFs, therefore the DEA does not regulate or inspect them;
- The DEA would be open to registering them as institutions similar to hospitals. However, such a change would require enabling legislation to be approved at the state level;
- Facilities complained that doctors often left off required information, such as drug strength or a signature. If prescriptions were written as required, medication could be dispensed immediately without a need to chase down doctors to correct the script.

Some issues were not addressed in the hearing. These included:

- If an LTCF becomes registered to stock its own drugs and administer based on orders, would a pharmacist be required to be onsite in their LTCF pharmacy?
- If LTCFs begin stocking their own drugs as hospitals do and prescriptions are no longer required, how would CMS payments be affected?

Medication Contracts—A Great Idea !!

The relationship between practitioner and patient is supposed to be based upon full information and open and honest communication. Unfortunately, practitioners often are besieged with drug-seeking patients who will go to great lengths to obtain additional drugs, prescriptions and refills. Obtaining or attempting to obtain controlled substances by fraud is a felony covered in Section 195.204.1, RSMo.

You Must Ask and Document Questions

The violation occurs when a person lies, misrepresents, uses deceit, fraud, or fails to disclose material information to his practitioner when receiving a controlled substance. The statute is violated when the patient lies or displays some type of dishonesty. To protect the integrity of drug supplies, it is imperative that medical staff ask questions. If you don't questions, then drug-seekers do not have to lie. The word will spread and many drug-seekers will come to your door. Be sure to ask and document information such as:

- What medications have you received for this?
- What medications are you on now?
- When was your last prescription for this?
- What other doctors have treated you for this?
- How many other practitioners are you seeing and for what?
- What medications have they provided to you?

Medication Contracts

These come under a variety of names and most practitioners draft their own for their patients. Some call them medication contracts, or patient contracts or treatment contracts or even pain-management contracts. The basic principles are the same. The practitioners protect themselves and also inform the patient regarding what is expected and what is not acceptable regarding how medications are handled. Regulatory agencies have always been in favor of these documents because it protects the medical community and deters drug seekers. Examples of some terms include, but are not limited, to:

- Patient shall not receive any medications from any other medical provider without notifying me within 24 hours;
- Patient shall report to me within 24 hours of visiting any emergency room;
- Patient agrees that I am their primary practitioner and my treatment shall be reported to any other medical practitioners providing treatment to them;
- Patients shall not obtain similar prescriptions for similar drug products from other practitioners;
- Patients shall take medications as directed and not take increased amounts so that refills are required sooner than authorized;
- Prescriptions will not be automatically replaced when it is reported drugs were stolen, lost, or eaten by the family pet;
- Patients shall not transfer or share their prescribed medicines with other persons;
- Patients shall not consume the prescriptions of another person;
- Patients shall use one pharmacy and shall NOT have multiple prescriptions filled from multiple doctors at multiple pharmacies;
- Patients shall not merely rely on prescriptions but must also cooperate with treatment by attending appointments and other treatment modalities and tests as scheduled;
- Patient is fully aware that lying, making false statements or representations to the medical staff or withholding material information regarding controlled substances can be a felony violation of Section 195.204.1, RSMo;
- Patient understands that violation of this contract is grounds for termination of care;
- Patient understands that making false statements and misrepresentations to this medical staff may result in reports being made to law enforcement. Fraudulent acts are not covered by HIPAA and are not confidential;
- Both the patient and a member of the medical staff should sign and date the agreement or contract;
- It should be retained in the patient's file.

It Has Been Proven to Work:

Recently the BNDD investigated a complaint regarding prescribing habits. The investigation found that the patient had visited 22 different doctors and obtained 76 prescriptions in 51 weeks at 8 different pharmacies. The patient had 3 separate pain contracts promising 3 different physicians that they were his only doctor. The doctors were protected and the patient was charged with fraud.

For further information on ways to stay current and protect your practice, visit the bureau's Web site at www.dhss.mo.gov/BNDD. Click on the link to Publications, and check out the booklet entitled *Preventing Prescription Fraud.*